Safer Births Bundle of Care - Keeping more mothers and babies safe during and after birth: A quality improvement implementation project in all health facilities with Comprehensive Emergency Obstetrics and Newborn Care Services in five regions in Tanzania.

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Summary

Background: Nearly 1.3 million fresh stillbirths (FSB) and 1 million newborn deaths occur in relation to birth each year globally. Moreover, approximately 300,000 women die of pregnancy and birth-related causes. The burden is unacceptably high in low-income countries, including Tanzania, especially around birth. Helping Babies Breathe (HBB) is an evidence-based training program that has proven to reduce neonatal deaths by 47% and intrapartum stillbirths (ISB) by another 24% when well implemented. Unfortunately, due to scarce resources and support post-implementation, the full potential of HBB is often not realized. To reduce this burden and appreciate the HBB potential, the Safer Births project (www.saferbirths.com) has successfully developed, implemented, and evaluated innovative clinical tools, training equipment, and strategies linked to automatic local data monitoring enabling relevant training for continuous quality improvement (CQI). The innovative **Safer Births Bundle of Care (SBBC)** results from 15 years of intensive work in Tanzania (from 2009 to 2024) through a strong consortium of national and international partners.

The intervention: SBBC is a co-created, validated, cost-effective, and well-proven package of several innovations, leading to better equipped, better trained, and better-supported healthcare workers (HCWs), with the opportunity and skills to provide improved and more timely care. The bundle includes **innovative clinical and training tools anchored to evidence-based training programs** and quality improvement components. Together these will highlight training needs, motivate local HCWs, stimulate a culture of excellence, and finally, provide a foundation for sustainable change.

Objective: To determine the impact (maternal and newborn deaths) of scaling up SBBC (therapeutic and training) on improving perinatal and maternal health in Tanzania mainland.

Methods: SBBC is a quality improvement project and now will be scaled up from 30 health facilities to 150 health facilities in Tanzania mainland for additional two years. The scale-up of SBBC will take place concurrently at additional 120 sites. The scale to 150 sites will include all sites providing Comprehensive Emergency Obstetric and Newborn Care (CEmONC) services in the five regions where SBBC phase 1 was implemented. SBBC is an integral part of the Tanzanian Ministry of Health (MoH) maternal and newborn health initiatives. The bundle's main focus is intrapartum care (i.e., labor-management using partograms and Moyo for fetal heart rate monitoring) and immediate newborn care, including newborn resuscitation (using Neobeat and upright bag and mask). Additional focus will include training and mentorship on the management of preeclampsia, difficulty deliveries, prolonged labour; and care of small and sick neonates including Kangaroo Mother Care (KMC). Further, the second phase will incorporate a client feedback system (Mama na Mwana) towards the enhancement of CQI initiatives, Support SBBC training through professional bodies to be recognized under Continuous Professional Development scheme. These will be coupled with Low Dose High Frequency (LDHF) on-job training using MamaNatalie and MamaBirthie simulators to manage difficult births and prevent bleeding after birth, as well as NeoNatalie live for newborn resuscitation. Periodic clinical and training site data (at the local health facility) will guide the training and continuous quality improvement. The already established simulation faculty will prepare simulation-based training with a follow-up mentorship provided in collaboration with Tanzania Midwifery Association (TAMA), Pediatric Association of Tanzania (PAT) and Association of Gynecologist and Obstetricians of Tanzania (AGOTA) to conduct the cascade of training in collaboration with national trainers. Likewise, there will be two trained local champions in each health facility implementing the bundle for close follow-up of the LDHF training and continuously sharing the clinical and training local data. We will implement a data collection system of for period collection of quantitative and qualitative data to support pragmatic evaluation of the interventions.

Budget: The total budget for the project, including the overhead and UNICEF administrative costs, is **TZS 18 billion.**

Introduction

Global annual rates of stillbirths, and neonatal and maternal mortality are unacceptably high, with most deaths occurring in low-income countries. Childbirth is regarded as a normal physiological, social, and cultural process, but it is prone to complications, which may lead to demise of the fetus, and the death of the newborn and/or the mother. Dying on the day of birth is still commonplace worldwide, making the focus on this day most crucial. There are considerable inequities in maternal and perinatal mortality and morbidity between countries, with the highest burden in Africa and South Asia. Globally, an estimated 2.2 million antepartum and intrapartum stillbirths (ISB), and 2.4 million neonatal deaths occur annually [1,2]. Of these, nearly a half are due to ISB and 1 million newborn deaths occur in relation to birth [3]. More than 80% of perinatal deaths occur in low-income countries (LIC), half in Sub-Saharan Africa, where the provision of service does not match the demand [1]. These deaths can be substantially reduced by improving the quality of care around the time of labor and childbirth [4].

Tanzania's neonatal mortality rate (NMR) was 24 per 1,000 live births (2022), translating to nearly 40,000 newborns deaths annually [5]. This neonatal mortality rate is far beyond the Sustainable Development Goal (SDG) target 3.2 of less than 12 deaths per 1000 live births [6]. The stillbirth rate was estimated to be as high as 20 deaths per 1000 births. Perinatal mortality (combined SB and neonatal deaths at seven days), considered being an indicator of the quality of care at delivery, was 38 deaths per 1000 births. Leading preventable causes of SB and neonatal deaths are intrapartum-related deaths, prematurity, and infections.

Most intrapartum-related deaths share a common hypoxic-ischemic pathway (birth asphyxia) [7]. Any interruption along the oxygen pathway results in reduced oxygen in fetal blood (hypoxemia) and tissue (hypoxia). Further hypoxia leads to ischemic heart and cerebral injury, resulting in (FSB and early neonatal deaths) and long-term adverse outcomes including neurodevelopmental impairment (about 1 million children annually). Around 10% of liveborn need basic resuscitation such as stimulation and positive pressure ventilation (PPV) to start breathing [8,9]. Resuscitated children have a higher risk of low IQ scores, [10] but children who recover quickly have similar scores for memory, attention and language as those being well at birth [11]. Almost all asphyxia-related fatalities are preventable by low-cost, basic, but prompt care at the time of birth. More timely obstetric interventions are known to decrease both maternal and perinatal morbidity and mortality [7,12,13]. Effective newborn resuscitation is crucial to reduce misclassified FSB (lifeless babies with heart activity who are not resuscitated) and asphyxia-related newborn deaths and impairment [8,14–16].

Furthermore, most countries with a high burden of poor maternal health outcomes, including Tanzania, did not meet MDG 5 (focusing on maternal health) targets by 2015, despite several concerted efforts to address maternal health challenges. In the SDG era, despite renewed efforts to reach less than 70 deaths per 100,000 births by 2030, maternal mortality remains a global challenge, especially in low/middle-income countries. Globally an estimated 300,000 maternal deaths occur annually [17]. Many deaths happen in the world's poorest countries without proper care. However, particularly in sub-Saharan Africa, while facility births are increasing, quality of care often does not follow. In Tanzania, the population has doubled over the past two decades, necessitating a doubling of health and social services to maintain coverage. There is reported increased facility births in Tanzania (81%), [18] and recent data estimate that the maternal mortality rate stands at 104/100,000 [5]. There are great uncertainties and ongoing discussions related to this recent estimate. Nevertheless, in response to increasing facility births and

continued high number of maternal deaths, there is a need to increase focus on improving the quality of care at birth, especially in low/middle-income countries, and address the low competency levels of HCWs in obstetrics [17,19,20].

Problem Statement

In 2022, Tanzania's neonatal mortality rate (NMR) was 24 per 1,000 live births, translating to nearly 48,000 newborns dying annually [5]. The stillbirth rate is estimated at 18 deaths per 1,000 births translating into 36,000 annual deaths. These deaths can be substantially reduced by improved quality of care around birth [4]. Data shows that 10% of live-born babies require basic resuscitation at birth, including bag-mask ventilation, to start breathing [8,9]. More timely obstetric interventions are known to decrease both maternal and perinatal morbidity and mortality [7,12,13]. Effective intrapartum fetal and newborn assessment and resuscitation are crucial to reducing asphyxia-related perinatal morbidity and mortality [8,14–16].

Tanzania's maternal mortality rate stands at 104/100,000, translating to 2,000 women dying in relation to pregnancy and childbirth annually [5]. Preventable causes of maternal mortality are postpartum hemorrhage (PPH), obstructed/prolonged labor, and (pre)-eclampsia.

An important pilot HBB study, conducted in 8 referral hospitals in Tanzania, showed a remarkable 47% reduction in all-cause newborn mortality within the first 24 hours of life and fresh stillbirths (FSB) by another 24% when well implemented. However, evaluation of scaled up in 15 of Tanzania's mainland regions showed a progressive decline in skills retention whereby immediately after HBB training, 87.1% of providers passed the objective structured clinical examination, and the number dropped to 79.4% at 4 to 6 weeks and 55.8% at 4 to 6 months. It has been further noted that one-day training used in Tanzania and elsewhere was too short and less effective in skills retention than frequent training supplemented with supportive supervision to reinforce skills. Furthermore, Delphi reviews field testing and frontline users of perinatal care and newborn resuscitation suggests that training of clinical staff should be augmented with simulation methods to build confidence and competence and additional guidance for facilitators on implementation [21]. Field trials refined approaches to self-reflection, data-driven feedback, and debriefing for quality improvement are essential in the implementation processes.

Globally, the significant investments made in improving access to and the availability of maternal and newborn care since the start of the MDG period in 2001 had a substantial impact on reducing the extent of the first and second delays of maternal and newborn care [22]. However, the third delay of inadequate quality of care remains a large challenge [23,24]. A Lancet publication showed that more deaths, including neonatal deaths, occur due to ***poor quality*** care than ***underutilization*** [25]. In response, there is a need to increase focus on improving the quality of care in facilities at birth to address the low competency levels of HCWs in obstetrics and newborn care [17,19,20]. Likewise, in Tanzania, as facility births are increasing - currently 81% in Tanzania [5] - the quality of care has not improved accordingly, leading to unnecessary maternal and perinatal mortality [5,26,27]. Incentivizing facility delivery, where competent, trained, and equipped HCWs provide good quality of care, is likely to result in desired perinatal and maternal outcomes. Health systems must be able to safeguard uncomplicated births and provide emergency obstetric and newborn care when needed [25,28]. In the halfway assessment of SBBC we noted an increased attention to data quality and use which may have a positive impact on the completeness of documentation [29]. SBBC is an ideal solution - it is cost-effective and feasible in both urban and rural low-resource settings with high burdens of maternal and perinatal morbidity and mortality. The recently published SBBC halfway evaluation describes an improved documentation, steady reduction in early newborn and maternal mortality, and fluctuation of reported

fresh stillbirths across times and regions[29,30].

Description of the innovation: The detailed description can be found in the published protocol [31]. The Safer Births Bundle of Care is a combination of innovative training and clinical tools tackling the main causes of perinatal deaths. The bundle results from 15 years of multidisciplinary collaboration among international institutions from in and outside Tanzania. Many of the innovations were co-created with midwives and doctors working in maternity departments of Haydom Lutheran Hospital (rural setting), Muhimbili National Hospital (urban setting), and engineers from Laerdal Global Health (Norway). All innovations are proven to be effective, efficient, and lifesaving. Almost 100 papers have been published in high-impact peer-reviewed international journals, evaluating and describing the bundle

Safer Births Bundle of Care	
	Moyo Fetal Heart Rate Monitor: Almost half of the global stillbirths are alive at the start of labor [32]. Fetal heart rate monitoring is critical for detecting fetuses at risk and saving lives [8]. Unfortunately, fetoscopes are the only available monitoring devices to detect fetuses at risk in low-resource settings, and they are less reliable and effective. Moyo has proven to be effective, user-friendly, and suitable for low-resource settings [33,34]. It can be used intermittently or continuously and provides audiovisual alarm, which enables HCWs to detect abnormal fetal heart rate patterns earlier and more often compared to fetoscope and hand-held Doppler devices. Moyo facilitates more timely decision-making [33–35] while reducing midwives' workload, as well as lessens maternal anxiety during labor as she can hear the heartbeat of her unborn baby [36–38].
	NeoBeat Newborn Heart Rate Meter: Current methods of measuring newborn heart rate in the first minutes of life are unreliable. Studies have shown that a significant number of babies are misclassified as FSB while alive at birth [7]. The underlying problem is often due to inadequate assessment of newborns immediately after birth, resulting in slow or no initiation of resuscitation. NeoBeat is a fast, easy and reusable device that provides an accurate and continuous display of a newborn's heart rate during the first seconds of life to remove this misclassifications and help guide resuscitation activities [39,40]. Well-trained HCWs using NeoBeat can initiate ventilation of non-breathing newborns within the first minute of life [Ref].
	Upright with PEEP Newborn Bag Mask: Compared to the horizontal bag-masks, the ergonomic orientation of the Upright bag-mask, and the new and improved Newborn Mask, are designed to make it easier to obtain mask seal and provide effective ventilations. Newborns with low-compliant (stiff) lungs were adequately ventilated with good outcomes using Upright with PEEP [41,42]
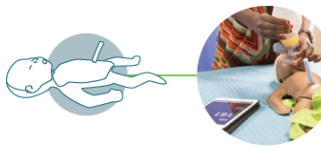
	NeoNatalie Live Newborn Resuscitation Trainer: NeoNatalie Live is a 'smart' simulator that provides feedback on key elements that providers often have difficulties with during newborn resuscitation. Each training session lasts less than 5 minutes and provides objective feedback on the ventilation performance. This ensures greater flexibility to healthcare providers to train whenever their busy schedules allow them to. NeoNatalie Live also track of individual and team training progress over time. This enables providers as well as management to have a better overview of the number of providers trained, training progress, and areas of improvement [papers in preparation].
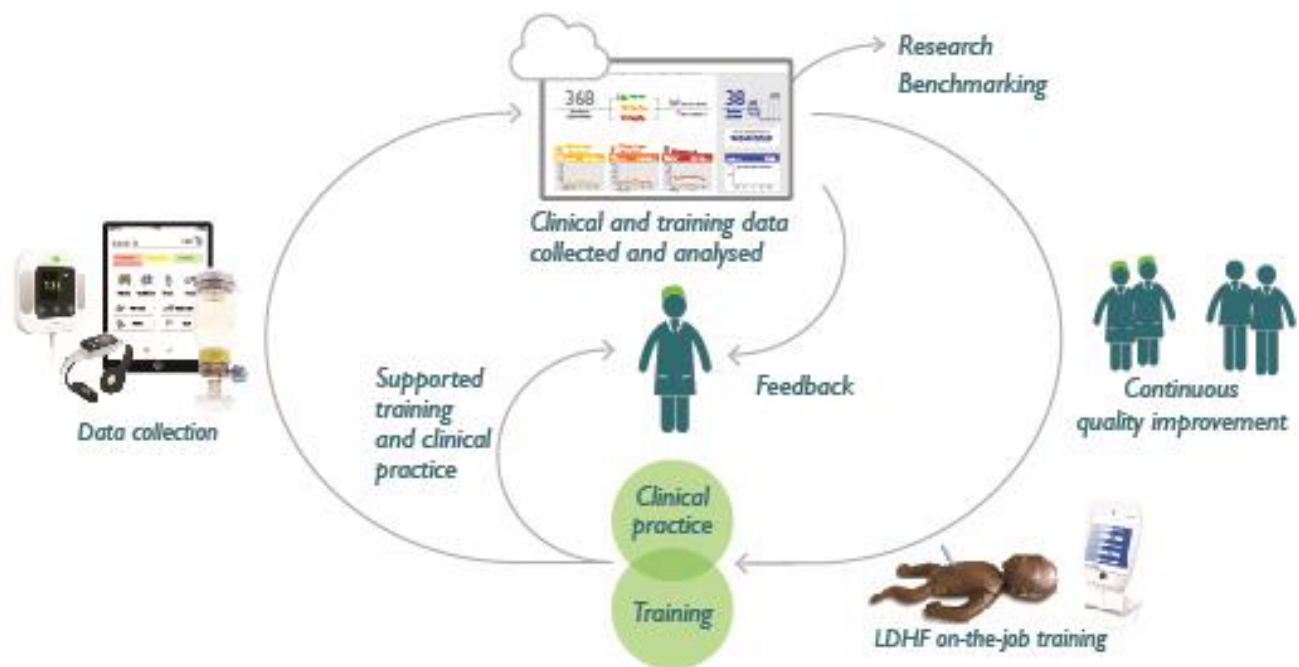
Rationale and Integration to global and country strategic plan

Inadequate care at birth impacts negatively perinatal and maternal outcomes. There are two targets in SDG 3 (i.e., SDG 3.1 and 3.2) related to quality-of-care provision at birth. SDG 3.1 target reduction of preventable maternal deaths and SGD 3.2 the under-5 mortality with a special focus on neonatal deaths [2]. Generating evidence-based knowledge on quality of care at birth is a key priority to reach these SDG goals, particularly on birth-related survival [2] but also in regards to societal development and poverty reduction (SDG 1 and SDG 5). Achieving the health-related SDGs is the function of healthcare systems. Facilities need to provide a safe and professional environment, enabling well-educated and skilled healthcare professionals to perform optimally with the resources available (SDGs 3c/4.7) [43,44]. This is simultaneously pivotal for enabling respectful working conditions for HCWs (SDG 8.8).

In Tanzania, to improve perinatal and maternal health, the Ministry of Health formulated a crosscutting strategy. This is the National Road Map strategic plan to improve reproductive, maternal, newborn, child, and adolescent health in Tanzania: the One Plan III (2021-2025), [45] which was built on the Health Sector Strategic Plan IV (HSSP 2011-2026) [46]. One Plan III aims to reduce perinatal mortality by 25% and maternal mortality by 75% by 2025 by improving coverage of essential newborn care (ENC) and safe motherhood by training to HCWs, which emphasizes Helping Babies Survive (HBS) and Helping Mothers

Survive (HMS) initiatives. Furthermore, ensuring the availability of newborn resuscitation equipment such as bag-mask resuscitators form components of the strategy. Recently, the ministry has embarked on a long-term plan of having all regional and district hospitals with functional neonatal care units, including equipment. As a part of HMS, the One Plan II emphasizes care during childbirth, including training and equipping HCWs with appropriate tools and devices for intrapartum monitoring of the fetus, the use of partograph, and provision of timely Emergency Obstetric and New-born Care (EmONC) as some of the strategies. Hence, the implementation of SBBC is much in line with the country's stipulated priorities.

The Safer Births Bundle of Care has been developed, implemented, and proven effective in changing clinical behavior and improving birth outcomes in both rural and urban Tanzanian hospitals since 2009. The innovations are not stand-alone products but rather integrate with and support the existing evidence based HBB training program. From research, we know that a one-day HBB training is not enough to change outcomes [47]. Experiences from the implementation of HBB in Tanzania show that low-dose high-frequency training (LDHF) and a culture of continuous quality improvement (CQI) within the facility are essential for retaining and translating skills from training into clinical practice and for helping save lives [16,48]. When well implemented, HBB shows reduction in newborn mortality by about 50% and fresh stillbirth by 25% [14]. However, there are often very scarce resources within the facility to support LDHF training and CQI efforts, and HBB trainings often do not realize their full potential. The data-capturing components of SBBC enable a system where HCWs can receive objective feedback on their trainings as well as the clinical quality of care. This not only helps guide their efforts but also brings motivation to find ways to continually improve. The HCWs' and facility leaders' assessment halfway through the implementation showed that they received the bundle well and regarded it as effective in saving lives and improving healthcare provision. They further elaborated that the bundle is appropriate to our needs, the training modality and data use fit our context, use of champions and periodic mentorship, learning from our mistakes, and clinical and training tools are of high quality but can be further improved [49]. It is therefore evident that increased perinatal survival worldwide is possible with a combination of evidence-based training programs (e.g., HBB) and innovative tools for treatment and training (e.g., Moyo, MamaNatalie, NeoBeat, NeoNatalie Live, Upright),

SBBC Phase I was implemented in 30 hospitals and the following are the lessons learnt:

- For health innovations to diffuse the HCWs should the center of the focus.
- The bundle is positively perceived and acceptability was high leading to constant call from regional authorities to scale up and include all CEmONC sites in the implementing regions [49].
- Strong local ownership and collaboration (from planning and during implementation) with the Government at all levels have been crucial for the achievements attained.
- Data-driven CQI efforts is a relative new practice in most of the facilities that is continuously embraced by the facilities. HCWs review clinical data they collect weekly and discuss strengths and area with weakness and plan improvement in the following week. The involvement of the whole maternity team (initially data were for the leaders only) in the review of data with guidance from facility champions has helped to keep the HCWs interested in understanding their own data.
- Quarterly mentorship and supportive supervisions are essential for uptake and sustainability. SBBC has supported quarterly Regional Health Management Team supervision in the five regions, of which the team is accompanied with SBBC regional coordinator and national TOT who facilitate supervision and mentorship.
- High rates of poor documentation especially the undesired maternal and perinatal outcomes. This has led to underestimation of stillbirths, especially at the beginning of the project implementation when collecting baseline information (data).
- High adoption rates as observed through clinical and training data collected at facilities.

- There have been staff rotation practice where those trained and equipped with delivery skills are shifted to other wards and new with less skilled located in labour ward. However, the presence of SBBC champions at the facility and the training tools (especially NeoNatalie Live and MamaNatalie) have facilitated peer to peer local capacity building through LDHF simulation based on-job training.

Proposed SBBC Implementation in Phase II

As of the halfway implementation, there are several documented positive implementation and health outcomes of SBBC phase I [29,30,49]. At the same time, the evaluation of the feasibility, adoption, sustainability, and cost, including the phase I implementation strategy will be considered in phase II. HLH and the government of Tanzania has jointly engaged in planning and implementing SBBC Phase II. The government of Tanzania through the Ministry of Health will provide strategic guidance. HLH in collaboration with the government of Tanzania will scale up using the similar model of training as in SBBC I to all remaining 120 CEmONC facilities in the original five regions while sustaining at the 30 facilities from phase I:

- Additional components of training/mentorship on the management of preeclampsia, difficulty deliveries, prolonged labour
- Training and equipping more than 3000 HCWs in all CEmONC sites in five regions.
- Continued strong focus on data driven CQI, facilitated by a new Data Management Platform, a Learning Improvement and Facilitation Tool (LIFT) under development by the main partners (HLH, Laerdal, SAFER, Stavanger University Hospital) that may facilitate the process of combining clinical and training data and adjust CQI efforts including training as needed on a local facility level.
- Collaborate with Ministry of Health to configure DHIS-2 to be able to automatically create a facility periodic dashboard for feedback to the HCWs strengthening CQIs
- Build a local "culture of excellence" using the same approach as previously – facility champions and mentors.
- Upgrading and standardizing training materials and modalities/strategies and follow-up of champions/mentorship
- Reduced focus on research and data collection, increased use of routine data from DHIS-2
- Build local capacity for maintaining and servicing SBBC equipment.
- Continue to capacitate the RHMT and CHMT in conducting supportive supervision of SBBC-related CQI, along with their routine supervision in the facilities.
- Incorporating a client feedback system (Mama na Mwana) towards the enhancement of CQI initiatives
- Support SBBC training through professional bodies to be recognized under Continuous Professional Development scheme.

Aim and objectives of SBBC phase II

Overall Aim

To optimize the components and implementation of SBBC, aligning closely with routine health system structures and processes, and to generate evidence of healthcare effects, feasibility, acceptability, sustainability, and cost-effectiveness to inform a national scale.

Specific Objectives

1. Increase coverage of SBBC in the original five regions from 21% to about 100% through (a) sustaining SBBC in the original 30 health facilities and (b) introducing SBBC in an additional 110 health facilities from 5 current SBBC regions using similar implementation model from SBBC I with additional training components on Eclampsia/preeclampsia, difficulty deliveries, prolonged labour; and care of small and sick neonates.
2. Link SBBC II training and CQI activities with the Continuous Professional Development (CPD) accreditation system.
3. Utilize Mama na Mwana client feedback in all SBBC II facilities to complement data-driven continuous quality improvement through promoting mothers' registration and engagement with the Mama na Mwana platform, and to include the data in Continuous Quality Improvement.
4. Integrate data collection and use within routine systems through health management of information systems registers, DHIS-2, and electronic medical records in all SBBC II regions.
5. Until essential variables are included in the DHIS-2 platform, SBBC Phase I will continue using the same data collection tool.
6. Utilize the LIFT system to make local training data readily available (dashboard) for internal CQ.
7. Promote the sustainability of procurement, maintenance capacity, and replacement plans for tools through engagement with MSD and the Ministry of Health procurement and Supply Unit, and train local biomedical technicians/engineers on the maintenance of innovative tools.
8. Generate evidence to inform national scale through (a) reduced but continued monitoring in the original 30 facilities and the additional 110 facilities in the five regions; (b) additional cost-effectiveness analyses.

Methods

Study design: This is a quality improvement project, which will be implemented simultaneously across all CEmONC sites in the five regions. Preparation period from December 2023 to April 2024, where readiness assessment and training of local champions will be conducted. The implementation period will start from April 2024 to December 2025.

Sites:

The project will be implemented at all CEmONC sites (approximately 150) across the five regions: Manyara, Tabora, Geita, Shinyanga, and Mwanza.

Implementation strategy

Haydom Lutheran Hospital is collaborating with TAMA, PAT, and AGOTA (locally) and international partners, including SUS, LGH, and SAFER, to scale up and ensure that implementation is rooted in local health organizations.

Sixteen members from TAMA/PAT/AGOTA have been trained as national SimBegin faculty. These faculty members will train 90 regional national facilitator (approximately 18 per region), mainly midwives, who will conduct the trainings for the SBBC II. The regional trainers will be selected mostly from SBBC I facility champions from participating health facilities. Building this capacity within these facilities and professional associations mean the value can be applied to not only the Safer Births project, but also other training initiatives around the country where simulation-based learning andragogy can be useful.

The leading team from HLH in collaboration with consortium partners will also conduct situational analysis close consultation with RHMT/CHMT and health facility administrations (Appendix 2). The aim is to assess and identify bottlenecks related to readiness, availability, and quality of care to be provided. The results of the assessment will be used to cater the implementation of the bundle. Also, baseline data will be collected to benchmarks key indicators for evaluation purposes (Appendix 3).
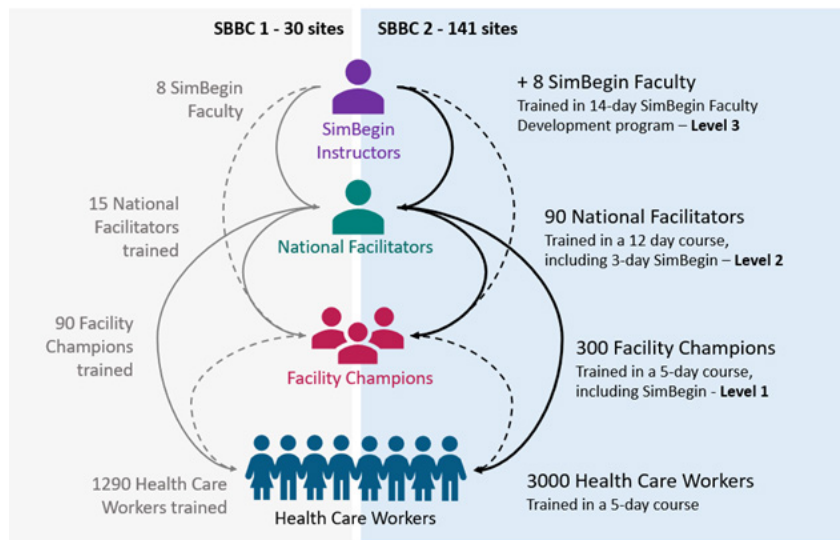
Two champions from each health facility will be identified and trained to be site facilitators. In total, there will be about 300 champions trained for six days in batches. They will be trained on the SBBC, where additional focus will lie on training in 1) the use of the innovative tools, 2) facilitation of LDHF on-the-job trainings, and 3) collection and use of local data for rapid feedback and P-D-S-A CQI. Standardized methods will be used to ensure the participants are sufficiently trained.

An onsite two-day training and a three-day clinical mentorship, targeting all HCWs and service providers available at the facility maternity ward, will follow the six-day training of site facilitators. It is estimated that 3000 HCWs will be trained in five regions. The facility champions will assist the national facilitators to conduct the training and mentorship. The 150 health facilities where SBBC will be implemented will be provided with the innovative tools for training, treatment, and data management, and these will remain at the facility beyond the project implementation period. With support from the regional project coordinators, the facility champions will be responsible for following up day-to-day duties in relation to the bundle and facilitating LDHF on-the-job trainings related to newborn resuscitation and different labor complications. Additionally, the facility champions will utilize the data captured to conduct periodic debrief meetings to enable HCWs' reflection on their care. Reinforcing competencies through regular LDHF simulation-based practice and providing specific and objective

data that highlights areas in need of improvement will motivate and guide HCWs on how to improve their care. This feedback will help translate knowledge and skills into clinical practice and establish a culture of excellence within the facilities. To ensure the facility champions are well supported in their new role, national facilitators, in collaboration with the district and regional coordinators, will conduct scheduled supportive supervision to provide in-house training and support on a regular basis.

Outcomes, Output, and process indicators of project implementation

Outcomes

Primary outcomes
1. Perinatal deaths defined as intrapartum stillbirth (ISB) or newborn death within the first 24 hours of life.
2. Maternal deaths within seven days postpartum.

Secondary outcomes:
1. 24-hour newborn deaths.
2. Intrapartum stillbirths (ISB).
3. 7-days perinatal deaths (including ISB).

Other process and output indicators
1. Antepartum stillbirths (ASB).
2. 2-7 days newborn deaths.
3. Proportion of deliveries followed by neonatal resuscitation (stimulation, suction, and bag-mask ventilation).
4. The attitudes, perceptions, and acceptability of SBBC among HCWs and health managers, as well as patient satisfaction, will be assessed.
5. Frequency of skills- and team-scenario trainings conducted in each facility, per number of relevant HCWs.
6. Frequency of mentorship/supportive supervision at each facility.

Study population and
The study will include pregnant women, newborns, and HCWs in all CEmONC sites in the five regions in Tanzania mainland. Pregnant women at gestation age of 28 weeks and above with a live fetus at recruitment will be enrolled in the study. All HCWs working in the maternity ward (prenatal, labor, postnatal, and neonatal wards) in the selected facility will be involved in this project.

Purposive sampling will be used in the qualitative components of the study. Maximum variation sampling will guide the selection of participants for in-depth interviews with HCWs, focus group discussions with the facility management team, as well as mother receiving interventions, their experiences of intrapartum care. This approach secures a wide range of people of interest and, consequently, a broad range of perspectives to understand better the contextual factors influencing implementation. Qualitative data will be collected until saturation is achieved.

Data collection

Implementation and training Process level data:
Training data from NeoNatalie Live. Systems will be established to document the dissemination of trainings and the frequency and quality (performance) of training among HCWs in each site over the two years. On-site simulation training data will be semi-automatically collected by a Learning Improvement and facilitation Tool (LIFT) system and the NeoNatalie Live simulator and uploaded automatically to the central server at Haydom.

- LIFT Assessments streamlines training program assessments through its innovative digital solution. Conducting facilitator-led assessments and collecting participant assessments digitally, LIFT Assessments eliminates the need for paper, reducing time and effort spent on manual data entry and analysis. With immediate feedback on participant performance through automated scoring, LIFT Assessments offers data-driven insights for progress tracking and informed decision-making.
- LIFT Scenarios aims to help guide and track simulation-based training at the facility level. LIFT Scenarios will guide facilitators on how to conduct seamless and powerful simulation-based trainings. It provides step-by-step guidance on each phase of training: briefing the participants before a simulation, supporting observation of key performance steps, and facilitating effective debriefs. The tool unlocks the potential of simulation-based trainings, helping to ensure participants translate their learnings into improved clinical care. The LIFT Scenario Training tool also supports tracking of simulation-based training data so that facilities can review their historical sessions. This enables facilities to adapt their training according to areas in need of improvement and follow-up on actions discussed by the team. The data from the trainings can also be viewed remotely by mentors and other stakeholders that are not within the facility. This ensures that facilities get the support and resources they need, sooner rather than later.

Clinical events/actions during intrapartum care will be collected from patient case notes, and labour and delivery registers. The use of clinical SBBC tools (Moyo, NeoBeat and Upright bag mask) will be recorded on separate data collection forms (Supplemental File). Biomedical heart rate signal data will be automatically collected by Moyo (fetal heart rate) and NeoBeat (newborn heart rate). Additionally, Moyo and NeoBeat will collect process data automatically.

Each region will have a project coordinator who will establish an independent data collection team to collect baseline data and implementation, process, output, and outcome level indicators. We will utilize the already trained data collectors (n=72). They will be responsible for 150 facilities each and visit each of these facilities twice a week. They will use the ODK tool kit for data collection. A health facility readiness and service availability assessment tool Appendix 1 will be used to conduct the bottleneck analysis of service readiness for intrapartum care at the start of the second phase of the project.

Clinical Outcome level data—data on mortality and clinical events during intrapartum care will be collected from Health Management of Information System (HMIS) book number 12, 13, 14 and death registers.

Data management
The clinical data collected at each health facility will be entered into an electronic data collection system (ODK). The data collectors will upload the data into electronic data collection system to the central database at Haydom Lutheran hospital via Internet. The data quality team at Haydom will perform quality data control in daily bases then submit clean data to a data manager. The data manager will perform final quality control before saving the data in the two secure servers. All clinical data will not include names; instead, the woman's file number will be used as her identifier.
The training data will be captured automatically by the innovative training tools, which will be uploaded automatically into a central server at Haydom. For other training data collected manually, it will be entered into the database immediately after training. The in-depth interviews, focus group discussions, diary reviews, and direct observations will be used to collect qualitative data. Further details will be outlined in a Data Management Plan (DMP).

Data storage and backup: Data will be stored in multiple ways, including a backup system. Data collected electronically using tablets will be transferred automatically and electronically to HLH, where two separate accounts in two different savers will be dedicated to this project. The first saver will be located in the saver room, with a backup in the second saver in the administration block. Signal data from Moyo and NeoBeat, as well as training data from NeoNatalie Live, will be electronically transferred and stored on a Haydom-specific server space (Microsoft). For security purposes, all electronic data (in tablets, computers, and servers) will be password-protected. The data will be de-identified to maintain the confidentiality of the participants.

Data analysis
Data analysis plans and strategies will be developed in collaboration with respective ministries and other partners in the consortium to answer specific project objectives. Quantitative data will be analyzed by using respective scientific guidelines such as STROBE [50]. Statistical process control methods will be utilized to monitor and analyze implementation and effects. Qualitative content data analysis methods will be used to analyze qualitative data. Qualitative data will be processed and analyzed using COREQ guidelines [51,52]. A Statistical Analysis Plan (SAP) will be published before finalization of data collection.

Ethical considerations
All research activities will conform to the Declaration of Helsinki and approvals will be sought from relevant facilities and ethical committees in Tanzania [53]. All women admitted into the labor ward for delivery will be verbally informed about the quality improvement project. They will be verbally informed about the tools used for fetal heart rate monitoring (Moyo and Pinard), tools for newborn resuscitation (Neobeat and bag mask). They will be informed that some of their data, as well as the routine data/information collected for their newborns during labor and delivery, will be used for evaluation purposes in a quality improvement program and will be anonymized.
However, women who will be recruited for interviews (in-depth and focus groups) will have written informed consent obtained (Appendix 5a and 5b). Only women and health facility staff aged 18 years and above will be recruited for in-depth interviews (IDIs) and focus group discussions (FGDs). All HCWs in the maternity ward of the facilities will be informed about the study and oral informed consent will be obtained from them (Appendix 4a and 4b).
All research assistants and investigators of the project will be trained on good clinical practice, research ethics, research integrity and confidentiality before starting the research. Management and storage of all data will be carried out in accordance with the governing laws in Tanzania. All data will be de-identified to maintain individual confidentiality.

Publication and dissemination strategy
Our findings will be published as multiple papers in peer-reviewed, relevant, Open-Access international journals and presented at global conferences. Permission to publish will be obtained before submission to peer-reviewed journals. A brief will be developed for policymakers outlining the required QI framework for improving care to advocate for more investments in such interventions. Combined workshops and dissemination seminars will be conducted with relevant stakeholders both locally and internationally. The aim will be to summarize and discuss the findings from the ongoing data collection, as well as the related implications for operational changes in care at birth and in the development and implementation of PDSA cycles as part of CQI.

Limitations of the study project
This is a quality improvement project aimed at enhancing the quality of care provision at the hospital level, which will ultimately impact maternal and neonatal outcomes. The project is focusing on the time of birth and immediately after birth. There are several limitations for this project, which includes: -
  i)   Less/lack of intervention on the pre-partum stillbirth, in which the fetus may have died before labor or before the woman reached the health facility.
  ii)   Inability to affect the undesired outcomes due to pre-existing (ANC) maternal conditions such as anemia, hypertension, diseases of pregnancy, infections (e.g., HIV/AIDS), and other disease conditions.
  iii)   Less/lack of effect on undesired outcomes due to congenital anomalies
  iv)   Less impact on the facility's infrastructural challenges
  v)   Inability to address the shortage of midwives and medical supplies beyond the innovative tools.
  vi)   Most of the data will be collected from clinical records, and this reduces the validity of the data in the research context.
  vii)   Several of the interventions will involve new innovative technology, and the adaptation of the technology will not be captured, even though it may affect the study outcome.

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